

## **IN THE CLAIMS**

1. (currently amended) An oral vaccine comprising a recombinant lactic acid bacterium capable of expressing a heterologous antigen intracellularly and/or on the surface of the bacterium, wherein the bacterium is *Lactobacillus plantarum* and can elicit an immune response ~~and/or immunogenicity~~ against the heterologous antigen.
2. (currently amended) [[A]] The vaccine according to claim 1 wherein the recombinant *Lactobacillus plantarum* comprises an expression vector capable of ~~causing expression of~~ expressing the heterologous antigen intracellularly and/or ~~exposure~~ on the cell surface, optionally under conditions present in the gastrointestinal tract.
3. (currently amended) [[A]] The vaccine according to claim 1 wherein the heterologous antigen can induce immunogenicity against a pathogenic microorganism, optionally a heterologous antigen specific for a mucosa colonising pathogen or pathogen entering the body via the mucosa, ~~such as via the oral route.~~
4. (currently amended) [[A]] The vaccine according to claim 1 wherein the heterologous antigen induces immunogenicity against a pathogenic microorganism colonising the gastrointestinal tract.
5. (currently amended) [[A]] The vaccine according to claim 1 wherein the heterologous antigen induces immunogenicity against a pathogenic ~~microorganism~~ organism selected from the group consisting of herpes virus, rubella virus, influenza virus, mumps virus, measles virus, poliomyelitis virus, rotavirus, respiratory syncytial virus, Campylobacter species, Chlamydial organisms, species of the genus *Cryptosporidium*, cytomegalovirus, human immunodeficiency virus, *Actinomyces* species, *Entamoeba histolytica*, arenaviruses, arboviruses, *Clostridium botulinum*, species of the genus *Candida*, *Vibrio* ~~cholera~~ cholerae, *Cryptococcus neoformans*, Enterohemorrhagic EHEC

strains of *E. coli* (EHEC), O157:H7, O26:H11, O111:H8 and O104:H21, Enterotoxigenic ETEC strains of *E. coli* (ETEC), strains of *E. coli* shown to possess enteroinvasiveness (EIEC), Enteropathogenic EPEC strains of *E. coli* (EPEC), Enteraggregative EaggEC strains of *E. coli* (EaggEC), Difficulty adhering DAEC strains of *E. coli* (DAEC), filoviridae, parvovirus, *Filarioidea*, *Staphylococcus aureus*, species of the genus *Clostridium perfringens*, *Helicobacter pylori*, Caliciviruses, *Giardia lamblia*, *Neisseria gonorrhoeae*, hantaviruses, hepatitis virus types A, B, C, D, and E, *Legionellae* strains, *Mycobacterium leprae*, *Listeria monocytogenes*, species of the genus *Clostridium perfringens*, *Borrelia burgdorferi*, *Pseudomonas pseudomallei*, Epstein Barr virus, *Onchocerca volvulus*, Poxvirus, *Bordetella pertussis*, *Yersinia pestis*, *Coxiella burnetii burnetii*, rabies virus, *Treponema palladium pallidum*, *Mycobacterium tuberculosis*, *Salmonella typhi*, a eukaryotic parasite causing malaria, *Pneumocystis pneumonia*, an agent causing toxoplasmosis, and any combination thereof.

6. (currently amended) [[A]] The vaccine according to claim 1 which elicits a protective response against a rotavirus, respiratory syncytial virus, *Mycobacterium tuberculosis*, human immunodeficiency virus, *E. coli*, *Vibrio cholerae cholerae*, streptococci and/or chlamydia.

7. (currently amended) [[A]] The vaccine according to claim 1 wherein the heterologous antigen is a viral and/or bacterial antigen optionally a gp160 envelope protein of the HIV virus, a surface glycoprotein of a *Leishmania* parasite, Shiga-like toxin, *Shigella* lipopolysaccharide antigen, *Escherichia coli* fimbrial antigen, a Coli Fimbrial Antigen (CFA) ~~CFA-antigen~~ of an enterotoxigenic *Escherichia coli* strain, anthrax toxin, pertussis toxin, or tetanus toxin.

8. (currently amended) [[A]] The vaccine according to claim 1 wherein the heterologous antigen is a human allergen or the heterologous antigen is specific for tetanus.

9. (currently amended) [[A]] The vaccine according to claim 1 which can induce protective immunity against the pathogenic organism that the antigen is from ~~immunogenicity~~.

10. (currently amended) [[A]] The vaccine according to claim 1 formulated as a single dose vaccine.

11. (currently amended) [[A]] The vaccine according to claim 1 wherein the recombinant *Lactobacillus plantarum* expresses the heterologous antigen intracellularly and/or [[an]] on the cell surface to a degree exceeding that of *Lactobacillus plantarum* 80 expressing  $\beta$ -galactosidase.

12. (currently amended) [[A]] The vaccine according to claim 1 wherein the recombinant *Lactobacillus plantarum* comprises a homologous expression and/or secretion signal, optionally in an expression vector for *Lactobacilli*, preferably for *Lactobacillus plantarum*.

13. (currently amended) [[A]] The vaccine according to claim 1 wherein the recombinant *Lactobacillus plantarum* strain exhibits a persistence in a vaccinated individual exceeding 5 days, preferably exceeding 9 days, suitably more than 15 or even 20 days.

14. (currently amended) [[A]] The vaccine according to claim 1 wherein the recombinant *Lactobacillus plantarum* exhibits a persistence longer than that of *L. plantarum* 80, preferably longer than that of *L. plantarum* NCIMB 8826, under equivalent conditions.

15. (currently amended) [[A]] The vaccine according to claim 1 formulated for ~~administration~~ administration to a human, ~~such as an infant, immunocompromised person, elderly person or a normally healthy infant, child or adult.~~

16. (currently amended) [[A]] The vaccine according to claim 1 wherein the recombinant *Lactobacillus plantarum* is a recombinant *Lactobacillus plantarum* 256.

17. (currently amended) [[A]] The vaccine according to claim 1 wherein the vaccine comprises at least one adjuvant or a pharmacologically acceptable carrier.

18. (currently amended) A recombinant *Lactobacillus plantarum*, optionally a recombinant strain of *Lactobacillus plantarum* 256, ~~as defined in vaccine claim 1~~ capable of expressing a heterologous antigen intracellularly and/or on the surface of the bacterium, wherein the bacterium can elicit an immune response against the heterologous antigen when the bacterium is administered orally.

19. (currently amended) [[A]] The bacterium according to claim 18 which is of non-human origin.

20. (currently amended) A non-human and/or non-human foodstuff *Lactobacillus* bacterium which has been modified to express a heterologous antigen and to elicit an immune response in an individual when administered orally.

21. (currently amended) [[A]] The bacterium according to claim 20 wherein:

- (a) the bacterium is a naturally occurring or unmodified *L. plantarum* is foreign to that individual or is not present in the gastrointestinal tract or mucosa of humans;
- (b) the antigen is expressed intracellularly and/or on the cell surface; and/or
- (c) the antigen is an immunogen.

22. (currently amended) A *Lactobacillus* bacterium which has been modified to express a heterologous antigen intracellularly and/or on the cell surface, to elicit an immune response in [[to]] an individual when administered orally and which can persist in the gastrointestinal tract of that individual for at least 7 days.

23. (currently amended) A *Lactobacillus* ~~organism~~ plantarum according to claim 18 which is ~~L. plantarum~~ or is for use in a vaccine.

24. (previously presented) An expression vector suitable for intracellular expression or exposure (on a cell surface) of a heterologous antigen, the expression vector being capable of providing expression in a *Lactobacillus plantarum* of the heterologous antigen under conditions existing in the gastrointestinal tract.

25. (currently amended) [[A]] The bacterium according to claim 19 for use in a method of prophylaxis or treatment of the human or animal body.

26. (withdrawn) A method of using a *Lactobacillus* bacterium which has been modified to express a heterologous antigen intracellularly and/or on the cell surface comprising administration of a vaccine to an individual for whom the unmodified *L. plantarum* is foreign.

27. (withdrawn) The method according to claim 26 wherein the unmodified *Lactobacillus* is *L. plantarum*, is not found in humans (the strain is endogenous) or is not present in the gastrointestinal tract or mucosa of mammals.

28. (withdrawn) A method of using a bacterium according to claim 19 comprising administration of a vaccine comprising said bacterium.

29. (withdrawn) The method according to claim 28 wherein the vaccine is adapted for oral administration and/or elicits an immune response on administration.

30. (withdrawn) The method according to claim 26 for treating or preventing tetanus.

31. (new) The vaccine according to claim 3 wherein the heterologous antigen is specific for a pathogen entering the body mucosally via the oral route.

32. (new) The vaccine according to claim 15, wherein the human is selected from the group consisting of an infant, immunocompromised person, elderly person, a normally healthy infant, a normally healthy child and a normally healthy adult.